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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office
D1439B

297 Plus Park Boulevard
Nashville, TN 37217

Received 2/23/98
JDH

February 23, 1998

Mr. Joseph Meier, President
Bluff City Medical Technologies, Inc.
5295 East Shelby Drive
Memphis, Tennessee 38118

WARNING LETTER - 98-NSV-08

Dear Mr. Meier:

During an inspection of your firm located in Memphis, Tennessee, on January 12-15 and 20-21, 1998 our investigator determined that your firm manufactures non-sterile orthopedic implants. Cervical spinal locking plates are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulation, as specified in Title 21 Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Device regulations were superceded on June 1, 1997, by the Quality System Regulation. Since the records reviewed were dated prior to June 1, 1997, the deficiencies noted during the inspection are cross referenced to the 1978 GMP.

The inspection revealed the following deviations from 21 CFR Part 820:

1. Failure to formally establish and implement audit procedures for planned and periodic audits to verify compliance with the quality assurance program.

2. Failure to have review procedures to assure that all records and documentation required for device history records (DHR) are complete and that devices are released for distribution only after a final quality

control inspection. For example, a review of twelve (12) work orders revealed the distribution of 353 units without a final quality control inspection.

3. Failure to validate computer operated manufacturing equipment and to always calibrate and maintain calibration records for quality control measuring equipment. For example, computer operated mills used in product manufacturing and micrometers and calipers used in product measurement.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closure of the inspection may be symptomatic of serious underlying problems in your firms manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuing of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submission for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Raymond K. Hedblad
Director, Nashville District

RKH/kl

Enclosures:
FDA-483
21 CFR Part 820

cc: Mr. Carl E. Beckalew
General Manager
Bluff City Medical Technologies, Inc.
5295 East Shelby Drive
Memphis, TN 38118